

Remarks

Upon entry of the forgoing amendment, claims 1-40, 43-67, 84-99, 102-115, 118-129, 132-133 and 136-138 are pending. Claims 41, 43, 68-83, 100-101, 116-117, 130-131 and 134-135 are sought to be cancelled without prejudice or disclaimer thereto. Claims 1, 4, 6, 42, 43, 46, 55, 63, 66, 84, 104, 107, 108, 110, 112, 120, 123, 124, and 126 are amended. Claim 138 is new. Claims 4, 6, 42, 55, 63, 66, 107, 108, 110, 112, 123, 124, and 126 are amended to correct claim formalities. Claims 1, 84, 104, and 120 are amended to include all of the limitations of cancelled claims 41 and 42, and specify that the basic amino acid is an arginine. Support for this amendment can be found in original claims 41 and 42, as well as the specification at paragraphs [0003] and [0039]. Likewise, claims 43 is amended to change its dependency from cancelled claim 42, to claim 1 which now includes all of the limitations of claim 42. Claim 46 is amended to specify that the host cell is a cultured host cell. Support for this amendment can be found in paragraph [0076]. New claim 138 contains all of the limitations of allowable claim 43, written in independent form. No new matter has been introduced by way of this amendment. Entry and consideration is respectfully requested.

Claim Objections

The claims have been amended to recite SEQ ID NO: X, instead of SEQ ID NO. X, as requested by the Examiner.

Claims 84, 107, and 108 have been amended to correct the typographical errors in formatting and specify that the subunit claimed is the α -subunit.

Claim 1 has been amended to correct the typographical error by deleting the “a” in the phrase “a ten fold.”

Claim 43 was objected to as being dependent upon a rejected base claim, but, according to the Examiner, would be allowable if rewritten in independent form. Independent claim 138 is herein introduced and includes all of the limitations of claim 43 and all base and intervening claims.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 4-6, 11, 12, 15, 26-28, and 40 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite due to an improper markush group. Claim 4 has been amended to include a proper markush group. Withdrawal of this rejection is earnestly solicited.

Rejections under 35 U.S.C. § 112, First Paragraph

Claim 46 is rejected under 35 U.S.C. § 112, first paragraph as not being enabled for host cells other than cultured host cells containing the vector of claim 45. Without agreeing with the Examiner's assertion, claim 46 has been amended in accordance with the Examiner's suggestion on page 8 of the Office Action to recite "a cultured host cell." Withdrawal of this rejection is therefore, earnestly solicited.

Rejections under 35 U.S.C. § 102

Claims 1-6, 11, 12, 15, 26-28, 40, 44-46, 52, 67, 84-93, 95, 97-99, 104-109, 111, 113-115, 120-123, 127-129, 136, and 137 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szkudlinski et al. (PCT Publ. No.: WO 97/42322) and Szkudlinski et al. (U.S. Patent Appl. Publ. No.: 2002/0110909). As recognized by the Examiner these are related patent applications and herein are referred to collectively as Szkudlinski.

Applicants have amended the claims to require all of the limitations of original claims 41 and 42, including that the modified FSH of the claims contains not only a modification in the α -subunit, but also a modification in the β -subunit, including an arginine at specified residues. These amendments render the Examiner's rejections in view of Szkudlinski moot because, as recognized by the Examiner, these publications do not teach or suggest the claimed modifications in the β -subunit. Withdrawal is earnestly solicited.

Claims 1-5, 41-42, 44-46, 52, 58, 67, 136, and 137 are rejected under 35 U.S.C. § 102(b) as being anticipated by Schambye et al. (U.S. Patent Appl. Publ. No.: 2002/0127652). Applicants respectfully traverse, however in an effort to advance prosecution, the claims have been amended to each require that the claimed modified FSH contains not only a modified α -subunit, but also a modified β -subunit comprising at least one basic amino acid at a position corresponding to positions 2, 4, 14, 63, 64, 67, and 69 of SEQ ID NO: 2, and further that the basic amino acid in the β -subunit is arginine. Schambye does not teach or suggest modifying the claimed positions with an arginine residue. Rather, Schambye teaches modifying select residues with a lysine in order to introduce a glycosylation site, *See* Schambye at paragraphs [0114]-[0116]. No where does Schambye teach or suggest modifying the claimed residues with arginine in order to achieve a 10 fold greater potency of the modified FSH when compared to wild type. Therefore, since Schambye does not teach or suggest each of the limitations of the claims, it cannot anticipate the claims under 35 U.S.C. § 102. Furthermore, since the purpose of Schambye (to introduce glycosylation sites) and the current invention (to increase strength of receptor binding) are different, Schambye does not render the claimed compositions obvious. Withdrawal of this rejection is earnestly solicited.

Rejections under 35 U.S.C. § 103

Claim 58 is rejected under 35 U.S.C. § 103(a) as being obvious over Szkudlinski in view of Schambye. Applicants respectfully traverse. Claim 58 depends ultimately from claim 1, which as discussed above has been amended to include each of the limitations of cancelled claims 41 and 42, and to specify that the basic amino acid modification in the β -subunit is an arginine. Also as discussed above, neither Szkudlinski nor Schambye teach or suggest these β -subunit modifications. Therefore, since claim 58 depends from claim 1, and therefore includes each of the limitations of claim 1, neither Szkudlinski nor Schambye alone or in combination teach each of the limitations of claim 58, and therefore cannot render it obvious. Withdrawal of this rejection is earnestly solicited.

Double Patenting Rejections

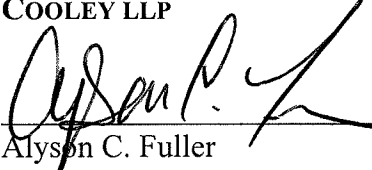
Claims 1-6, 11, 12, 15, 26-28, 40, 44-46, 52, 136 and 137 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. 7,070,788 and claim 58 is similarly rejected over 7,070,788 in view of Schambye. Applicants respectfully traverse. Since all claims now include each of the limitations of cancelled claims 41 and 42, which are not rejected on the grounds of obviousness-type double patenting, this rejection is rendered moot. Withdrawal is respectfully requested.

In view of the foregoing, Applicant respectfully submits that no further impediments exist to the allowance of this application and, therefore, requests an indication of allowability. However, the Examiner is requested to call the undersigned if any questions or comments arise.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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